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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/403,690	01/26/00	PFEFFER	K	20239-706

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EXAMINER	
EINSMANN, J	
ART UNIT	**PAPER NUMBER**
1655	10

DATE MAILED: 06/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/403,690	PFEFFER, KLAUS	
	Examiner	Art Unit	
	Juliet C. Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of a gene encoding enterotoxigenic E. coli heat labile toxin. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 1 and 2 or using oligonucleotide primers SEQ ID NO: 1 and 2 in combination with oligonucleotide probe SEQ ID NO: 19 wherein the oligonucleotide primers/probes are specific for a gene encoding enterotoxigenic E. coli heat labile toxin.

B. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of a gene encoding enterotoxigenic E. coli heat stable toxin. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 3 and 4 or using oligonucleotide primers SEQ ID NO: 3 and 4 in combination with oligonucleotide probe SEQ ID NO: 20 wherein the oligonucleotide primers/probes are specific for a gene encoding enterotoxigenic E. coli heat stable toxin.

C. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of a gene encoding enteroaggregative E. coli heat stable toxin. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 5 and 6 or using oligonucleotide primers SEQ ID NO: 5 and 6 in combination with oligonucleotide probe SEQ ID NO: 21 wherein the oligonucleotide primers/probes are specific for a gene encoding enteroaggregative E. coli heat stable toxin.

D. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the pCVD432 plasmid for amplification of a DNA

sequence characteristic for enteroaggregative E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 7 and 8 or using oligonucleotide primers SEQ ID NO: 7 and 8 in combination with oligonucleotide probe SEQ ID NO: 22 wherein the oligonucleotide primers/probes are specific for the pCVD432 plasmid for amplification of a DNA sequence characteristic for enteroaggregative E. coli.

E. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the inv-plasmid for amplification of a DNA sequence contained in enteroinvasive E-coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 9 and 10 or using oligonucleotide primers SEQ ID NO: 9 and 10 in combination with oligonucleotide probe SEQ ID NO: 23 wherein the oligonucleotide primers/probes are specific for the inv-plasmid for amplification of a DNA sequence contained in enteroinvasive E-coli.

F. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of EAF plasmid for amplification of a DNA sequence characteristic for enteropathogenic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 11 and 12 or using oligonucleotide primers SEQ ID NO: 11 and 12 in combination with oligonucleotide probe SEQ ID NO: 24 wherein the oligonucleotide primers/probes are specific for EAF plasmid for amplification of a DNA sequence characteristic for enteropathogenic E. coli.

G. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the eae gene for amplification of a DNA sequence characteristic for enteropathogenic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 13 and 14 or using oligonucleotide primers SEQ ID NO: 3 in combination with oligonucleotide probe SEQ ID NO: 25 wherein the oligonucleotide primers/probes are specific for the eae gene for amplification of a DNA sequence characteristic for enteropathogenic E. coli.

H. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification of the gene encoding shiga-like toxin sltI for amplification of a DNA sequence characteristic for enterohemorrhagic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 15 and 16 or using oligonucleotide primers SEQ ID NO: 15 and 16 in combination with

oligonucleotide probe SEQ ID NO: 26 wherein the oligonucleotide primers/probes are specific for the gene encoding shiga-like toxin sltI for amplification of a DNA sequence characteristic for enterohemorrhagic E. coli.

I. Claims 2-3, 6-7, 11-12, and 14-15 (all partially)

Methods and oligonucleotides for the detection of pathogenic E. coli in a sample comprising PCR amplification a gene encoding shiga-like toxin sltII for amplification of a DNA sequence characteristic for enterohemorrhagic E. coli. Preferred embodiments include methods which employ oligonucleotide primers with SEQ ID NO: 17 and 18 or using oligonucleotide primers SEQ ID NO: 17 and 18 in combination with oligonucleotide probe SEQ ID NO: 27 wherein the oligonucleotide primers/probes are specific for a gene encoding shiga-like toxin sltII for amplification of a DNA sequence characteristic for enterohemorrhagic E. coli.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner: Claims 2-3, 6-7, 11-12, and 14-15 all contain the species listed above.

The following claim(s) are generic: 1, 4-5, 8-10, 13, and 16-20.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species is drawn to methods of detection and

or/products specific to a different gene or plasmid from different groups of E.coli. These genes and plasmids are structurally different molecules encoding different products with different linear nucleic acid sequences. Therefore, they are considered lack unity because they lack a special technical feature.

4. A telephone call was made to Carol Gruppi on 6/21/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C. Einsmann
Examiner
Art Unit 1655

June 22, 2000